NOV 2 8 2001

K013581

510(k)
Summary of Safety and Effectiveness

Submitter: Cordis Corporation, a Johnson & Johnson Company
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Warren, New Jersey 07059

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Date Prepared: October 26, 2001

Trade Name: Cordis **AVIATOR™** Peripheral Dilatation Catheter

Common Name: Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter

Classification Name: (unclassified; FDA product code LIT)

Device Classification: Class II

Summary of Substantial Equivalence:
The design, materials, specifications, performance, packaging and intended use featured with the Cordis AVIATOR Peripheral Dilatation Catheter are substantially equivalent to those featured among the following predicate devices:

- Cordis **OPTA®** LP PTA Catheter (ref. K971448 and K981407);
- Cordis **SLALOM™** .018 PTA Balloon Catheter (ref. K003159);
- Cordis M3 PTA Dilatation Catheter (ref. K003920); and,
- Guidant **AVIATOR** Peripheral Dilatation Catheter (ref. K010831).

In short, the subject **AVIATOR** Peripheral Dilatation Catheter represents a line extension to the predicate Cordis devices that introduces substitute catheter materials.

Device Description:
The **AVIATOR** Peripheral Dilatation Catheter has an integrated shaft system and a balloon near the distal tip. The shaft has a combination of single lumen and dual lumen tubing. One lumen is used for inflation of the balloon with contrast medium. The second lumen, located only in the distal shaft, permits the use of a .014" diameter guidewire to facilitate the advancement of the catheter to and through the stenosis to be dilated. The catheter shaft has a distal port (hole) near the distal end that accesses the guidewire lumen. The guidewire lumen begins at the distal port and ends at the distal tip. This "rapid exchange" design allows insertion and removal of the catheter without extension of the guidewire.

The balloon has radiopaque marker(s) to aid in positioning the balloon. The balloon is further designed to provide an expandable segment of known diameter and length at a specific pressure.

The design of this catheter does not incorporate a lumen for distal dye injections or distal pressure measurements.

A flushing needle accessory is also provided with the device to facilitate flushing/lubricating the catheter's inner guidewire lumen prior to use.

The **AVIATOR** Peripheral Dilatation Catheter is provided sterile and is intended for single use only.

Intended Use:
The **AVIATOR** Peripheral Dilatation catheter is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra popliteal, renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Technological Characteristics:
The subject **AVIATOR** Peripheral Dilatation Catheter incorporates substantially equivalent indications for use, design, and dimensional and performance specifications as those found with the aforementioned predicate devices. The **AVIATOR** Peripheral Dilatation Catheter is provided in a range of expanded diameters from 4 to 7 mm and in lengths of 15 to 40 mm. The device features a useable catheter length of 75 to 135 cm.

Performance Data:
The safety and effectiveness of the Cordis **AVIATOR** Peripheral Dilatation Catheter have been demonstrated via data collected from non-clinical tests and analyses, which addressed the following, among other considerations, as determined necessary per applicable risk analyses:

- Biocompatibility

- Balloon minimum burst strength
- Balloon compliance (distensibility)
- Balloon inflation/deflation performance
- Balloon fatigue (repeated balloon inflation) endurance
- Bond strengths
- Catheter diameter and balloon profile
- Catheter body minimum burst strength

A statement of substantial equivalence to another product is required by 21 CFR 807.87 and relates only to whether the present product can be marketed without prior reclassification or clinical approval. The present submission is therefore not related to the coverage of any patent and is not to be interpreted as an admission or used as evidence in a patent infringement lawsuit. As the commissioner of the stated, "A determination of substantial equivalence under the Federal Food, Drug and Cosmetic Act related to the fact that the product can be lawfully marketed without pre-market approval or reclassification. This determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits." 42 Federal Register 42, 50 et seq. (1977).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Chuck Ryan
Manager, Regulatory Affairs
Cordis Corporation, a Johnson & Johnson Company
7 Powder Horn Drive
Warren, NY 07059

Re: K013581
Trade Name: Cordis AVIATOR™ Peripheral Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY and LIT
Dated: October 26, 2001
Received: October 29, 2001

Dear Mr. Ryan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4645. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013581

Device Name: **Cordis AVIATOR Peripheral Dilatation Catheter**

Indications for Use Statement

The **Cordis AVIATOR Peripheral Dilatation catheter** is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra popliteal, renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Division of Cardiovascular & Respiratory Devices
510(k) Number K01 3581

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use_____